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# FEDERAL TRADE COMMISSION

[BILLING CODE: 986750-01S]

[File No. 151 0236]

Valeant Pharmaceuticals International, Inc.; Analysis to Aid Public Comment

**AGENCY:** Federal Trade Commission.

**ACTION:** Proposed Consent Agreement.

**SUMMARY:** The consent agreement in this matter settles alleged violations of federal law prohibiting unfair methods of competition. The attached Analysis to Aid Public Comment describes both the allegations in the complaint and the terms of the consent order -- embodied in the consent agreement -- that would settle these allegations.

**DATES:** Comments must be received on or before December 7, 2016.

**ADDRESSES:** Interested parties may file a comment at

https://ftcpublic.commentworks.com/ftc/valeantparagonpelicanconsent

online or on paper, by following the instructions in the Request for Comment part of the

**SUPPLEMENTARY INFORMATION** section below. Write "In the Matter of Valeant

Pharmaceuticals International, Inc., File No. 1510236" on your comment and file your comment

online at <a href="https://ftcpublic.commentworks.com/ftc/valeantparagonpelicanconsent">https://ftcpublic.commentworks.com/ftc/valeantparagonpelicanconsent</a>

by following the instructions on the web-based form. If you prefer to file your comment on

paper, write "In the Matter of Valeant Pharmaceuticals International, Inc., File No. 1510236" on

your comment and on the envelope, and mail your comment to the following address: Federal

Trade Commission, Office of the Secretary, 600 Pennsylvania Avenue, NW, Suite CC-5610

(Annex D), Washington, DC 20580, or deliver your comment to the following address: Federal

Trade Commission, Office of the Secretary, Constitution Center, 400 7th Street, SW, 5th Floor,

Suite 5610 (Annex D), Washington, DC 20024.

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**FOR FURTHER INFORMATION CONTACT:** Charles Harwood, FTC Northwest Regional Office, 915 Second Ave., Room 2896, Seattle, WA 98174 (206-220-4480).

SUPPLEMENTARY INFORMATION: Pursuant to Section 6(f) of the Federal Trade Commission Act, 15 U.S.C. 46(f), and FTC Rule 2.34, 16 CFR 2.34, notice is hereby given that the above-captioned consent agreement containing consent order to cease and desist, having been filed with and accepted, subject to final approval, by the Commission, has been placed on the public record for a period of thirty (30) days. The following Analysis to Aid Public Comment describes the terms of the consent agreement, and the allegations in the complaint. An electronic copy of the full text of the consent agreement package can be obtained from the FTC Home Page (for November 7, 2016), on the World Wide Web, at http://www.ftc.gov/os/actions.shtm.

You can file a comment online or on paper. For the Commission to consider your comment, we must receive it on or before December 7, 2016. Write "In the Matter of Valeant Pharmaceuticals International, Inc., File No. 1510236" on your comment. Your comment - including your name and your state - will be placed on the public record of this proceeding, including, to the extent practicable, on the public Commission Website, at <a href="http://www.ftc.gov/os/publiccomments.shtm">http://www.ftc.gov/os/publiccomments.shtm</a>. As a matter of discretion, the Commission tries to remove individuals' home contact information from comments before placing them on the Commission Website.

Because your comment will be made public, you are solely responsible for making sure that your comment does not include any sensitive personal information, like anyone's Social Security number, date of birth, driver's license number or other state identification number or foreign country equivalent, passport number, financial account number, or credit or debit card number. You are also solely responsible for making sure that your comment does not include any sensitive health information, like medical records or other individually identifiable health

information. In addition, do not include any "[t]rade secret or any commercial or financial information which . . . is privileged or confidential," as discussed in Section 6(f) of the FTC Act, 15 U.S.C. 46(f), and FTC Rule 4.10(a)(2), 16 CFR 4.10(a)(2). In particular, do not include competitively sensitive information such as costs, sales statistics, inventories, formulas, patterns, devices, manufacturing processes, or customer names.

If you want the Commission to give your comment confidential treatment, you must file it in paper form, with a request for confidential treatment, and you have to follow the procedure explained in FTC Rule 4.9(c), 16 CFR 4.9(c). Your comment will be kept confidential only if the FTC General Counsel, in his or her sole discretion, grants your request in accordance with the law and the public interest.

Postal mail addressed to the Commission is subject to delay due to heightened security screening. As a result, we encourage you to submit your comments online. To make sure that the Commission considers your online comment, you must file it at <a href="https://ftcpublic.commentworks.com/ftc/valeantparagonpelicanconsent">https://ftcpublic.commentworks.com/ftc/valeantparagonpelicanconsent</a> by following the instructions on the web-based form. If this Notice appears at <a href="http://www.regulations.gov/#!home">http://www.regulations.gov/#!home</a>, you also may file a comment through that website.

If you file your comment on paper, write "In the Matter of Valeant Pharmaceuticals International, Inc., File No. 1510236" on your comment and on the envelope, and mail your comment to the following address: Federal Trade Commission, Office of the Secretary, 600 Pennsylvania Avenue, NW, Suite CC-5610 (Annex D), Washington, DC 20580, or deliver your comment to the following address: Federal Trade Commission, Office of the Secretary,

<sup>&</sup>lt;sup>1</sup> In particular, the written request for confidential treatment that accompanies the comment must include the factual and legal basis for the request, and must identify the specific portions of the comment to be withheld from the public record. *See* FTC Rule 4.9(c), 16 CFR 4.9(c).

Constitution Center, 400 7th Street, SW, 5th Floor, Suite 5610 (Annex D), Washington, DC. If possible, submit your paper comment to the Commission by courier or overnight service.

Visit the Commission Website at <a href="http://www.ftc.gov">http://www.ftc.gov</a> to read this Notice and the news release describing it. The FTC Act and other laws that the Commission administers permit the collection of public comments to consider and use in this proceeding as appropriate. The Commission will consider all timely and responsive public comments that it receives on or before December 7, 2016. You can find more information, including routine uses permitted by the Privacy Act, in the Commission's privacy policy, at <a href="http://www.ftc.gov/ftc/privacy.htm">http://www.ftc.gov/ftc/privacy.htm</a>.

## **Analysis of Agreement Containing Consent Order to Aid Public Comment**

The Federal Trade Commission ("Commission") has accepted for public comment an Agreement Containing Consent Order ("Consent Order") with Valeant Pharmaceuticals International, Inc. ("Valeant") to remedy the alleged anticompetitive effects resulting from Valeant's acquisition of Paragon Holdings I, Inc., including wholly-owned subsidiaries Paragon Vision Sciences, Inc. and CRT Technology, Inc. ("Paragon").

The Complaint alleges that the acquisition violated Section 7 of the Clayton Act, as amended, 15 U.S.C. 18, and Section 5 of the Federal Trade Commission Act, as amended, 15 U.S.C. 45, by lessening competition in the markets for polymer discs, or "buttons," used to make three different types of rigid gas permeable ("GP") contact lenses: orthokeratology contact lenses, large-diameter scleral contact lenses, and general vision correction contact lenses. The Consent Order would remedy the alleged violations by restoring competition in these GP button markets.

Under the terms of the Consent Order, Valeant is required to divest Paragon in its entirety, including the assets of Pelican Products LLC ("Pelican"), a manufacturer of contact lens packaging.

The proposed Consent Order has been placed on the public record for 30 days to solicit comments from interested persons. Comments received during this period will become part of the public record. After 30 days, the Commission will again review the proposed Consent Order and any comments received, and decide whether the Consent Order should be withdrawn, modified, or made final.

#### 1. THE PARTIES

Valeant is a Canadian conglomerate that develops and markets prescription and non-prescription pharmaceutical products. Through its subsidiary Bausch + Lomb, Valeant is a leading producer of GP buttons used to make GP contact lenses. Prior to its acquisition by Valeant in May 2015, Paragon was a United States corporation with its principal place of business in Arizona. Paragon produces GP buttons used to make GP contact lenses and also produces finished GP lenses.

After the Paragon acquisition, Valeant also purchased Pelican, a manufacturer of contact lens packaging, and the only producer of FDA-approved vials for wet-shipping finished orthokeratology lenses. Pelican became a subsidiary of Paragon. This acquisition ensured Valeant's access to the vials, after Pelican's owner announced plans to exit the market.

## 2. THE RELEVANT MARKET

Both parties engage in developing, manufacturing, and selling GP buttons in the United States. The relevant product markets in which to analyze the effects of the acquisition are the manufacture and sale of FDA-approved GP buttons for: orthokeratology GP lenses, which are worn to reshape the cornea; large-diameter scleral GP lenses, which cover the white of the eye and are used post-surgery, for transplants, and to treat eye disease; and general vision correction GP lenses. Each type of GP lens requires a GP button with parameters unique to that lens type.

GP lenses are used, and in some cases are medically necessary, to address a variety of

vision problems, including dry eyes, abnormal curvatures of the eye, corneal disease, post-eye surgery complications, and eye trauma. Optical labs use GP buttons to make GP contact lenses to fulfill prescriptions from eye care professionals. Prescriptions typically specify a particular product and brand of button, and eye care professionals invest significant capital in fitting equipment for the brands they prescribe.

The FDA requires that GP lenses must be made from FDA-approved GP buttons. Thus, there are no alternatives to FDA-approved GP buttons for making each of the types of GP lenses and the relevant geographic market is the United States.

Prior to the acquisition, Valeant and Paragon independently produced buttons for all three types of GP lenses. In the market for orthokeratology GP buttons, the combination of Valeant and Paragon was a merger to monopoly. In the market for scleral GP buttons, the combined company accounted for 70-80 percent of the market. In the market for general vision correction GP buttons, the combined company's market share was approximately 65-75 percent.

# 3. EFFECTS OF ACQUISITIONS

The acquisition likely caused significant competitive harm in the relevant markets. Specifically, the acquisition of Paragon eliminated actual, direct, and substantial competition between Valeant and Paragon in the relevant markets for GP buttons and allowed Valeant to unilaterally exercise market power. For instance, following the acquisition, Valeant increased prices in all three GP button markets.

Prior to the acquisition, Valeant and Paragon also competed on innovation, with the incentive to develop new GP lens buttons and improve button materials by investing in research, development, and adoption. This innovation led to broader product lines, improvements to button materials, and marketing and education funding for optical labs. The acquisition also eliminated this innovation competition between Valeant and Paragon.

#### 4. ENTRY AND EFFICIENCIES

Entry into the relevant market has not been, and would not be, timely, likely, or sufficient to deter or counteract the anticompetitive effects of the acquisition. Optical labs have limited short-term ability to switch from Valeant and Paragon, which supply the majority of their GP scleral buttons and GP general vision correction buttons, and 100 percent of their GP orthokeratology buttons. Optical labs might try to persuade eye care professionals to switch to a different material and brand, but ultimately the decision is made by the eye care professional, for whom such a change is costly and time-consuming.

Considerable entry barriers also arise from the FDA approval process. For GP orthokeratology buttons, the FDA premarket approval process takes several years because finished orthokeratology lenses worn overnight are Class III medical devices. For GP scleral and general vision buttons, the FDA premarket notification process likely requires at least one year, as the finished lenses incorporating such buttons are Class II medical devices.

We did not find any evidence of efficiencies that would outweigh the competitive concerns arising from the Paragon acquisition.

## 5. CONSENT ORDER

The proposed Consent Order requires Valeant to divest Paragon in its entirety no later than ten (10) days after the order date, to remedy the concerns raised by the acquisition and restore competition in the relevant markets by instituting Paragon as an independent, viable competitor to Valeant. The proposed Consent Order also requires Valeant to divest Pelican with Paragon to ensure continued access to FDA-approved vials for shipping its finished lenses.

The proposed Consent Order requires that Valeant must divest Paragon and Pelican to

Paragon Companies LLC in an upfront transaction. Paragon Companies LLC is a newly created

entity owned by Joe Sicari. Mr. Sicari was the president of Paragon prior to its acquisition by

Valeant in May 2015.

The Commission may, at any time, appoint a Monitor with the power and authority to

ensure that Valeant fulfills all obligations and responsibilities under the Consent Order and

Divestiture Agreement.

The Consent Order will remain in effect for ten (10) years, and contains standard

compliance and reporting requirements.

By direction of the Commission.

Donald S. Clark

Secretary.

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